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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,189	01/23/2001	Stuart B. Levy	PKZ-021CP	1931

959 7590 05/22/2003

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/22/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/768,189	LEVY ET AL.
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-29, 31-41 and 44-70 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 10, 11, 15-18, 22-27, 29, 31, 32, 52, 53, 56 and 57 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5, 9, 12-14, 19, 28, 33-41, 44-51, 54, 55 and 58-70 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> .	6) <input type="checkbox"/> Other: _____

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Double Patenting***

2. **The provisional rejection of claims 1-5, 9, 12-14, 19, 33-41, 44-51, 54 and 59-70 under the judicially created doctrine of obviousness-type double patenting over claims 77 and 81 of copending Application No. 09/823,884 is maintained.**

Applicant's statement that the double patenting issue will be addressed upon a finding of allowable subject matter in one of the two applications is noted.

3. **The provisional rejection of claims 30, 42 and 43 under the judicially created doctrine of obviousness-type double patenting over claims 77 and 81 of copending Application No. 09/823,884 is made moot by the cancellation of the instant claims.**

***Claim Rejections - 35 USC § 112***

4. **The rejection of claims 1-5, 9, 12-14, 19-21, 28, 33-39, 44-51, 54, 55 and 58-70 under 35 USC 112, second paragraph is withdrawn.**

**5. The rejection of claims 30, 42 and 43 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.**

**6. Claims 78-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The claims are indefinite because of the recitation of the phrase "a prodrug moiety". The present specification lacks definition of said phrase and, thus, the skilled artisan in the art would be unable to determine what is encompassed by the phrase. Therefore, he would be unable to determine the metes and bound of the claimed invention.

***Claim Rejections - 35 USC § 102***

**7. The rejection of claims 1-5, 9, 12-14, 19, 33-37 and 39-41 under 35 USC 102(a) over Armson et al. is withdrawn.**

**8. The rejection of claim 30 under 35 USC 102(a) over Armson et al. is made moot by the cancellation of the instant claim.**

***Claim Rejections - 35 USC § 103***

**9. The rejection of claims 38, 44-51, 54 and 59-70 under 35 USC 103(a) over Armson et al. is maintained and claims 1-5, 9, 12-14, 19, 33-37 and 39-41 are rejected under 35 USC 103(a) over Armson et al.**

Applicant argues the reference does not teach or suggest the use of tetracycline compounds to control *Cryptosporidium parvum* in mammals wherein the compounds inhibit more than 70% of *Cryptosporidium parvum* at concentrations of less than 10 $\mu$ g/ml. Applicant's argument was considered but not persuasive for the following reasons.

In the medical/pharmaceutical art, one of the first lines of obtaining pharmaceuticals for specific disorders is the screening of chemicals/compounds utilizing assays developed to test the activity of compounds against said disorders.

Extrapolation of in vitro determinations to in vivo models is routinely done in the art. In the case of Armson, the in vitro testing resulted in the determination that doxycycline has significant anticryptosporidial activity. Extrapolation of results obtained by the Armson to in vivo would be routine in the art. The skilled artisan would have the reasonable expectation that the anticryptosporidial activity of doxycycline taught by Armson would be seen in in vivo models. Therefore, the claimed method of using the prior art compound is *prima facie* obvious in view of the teachings of the cited prior art and the level of skill of the ordinary artisan in the art at the time of the instant invention.

Applicant also argues the reference does not teach or suggest inhibition of more than 70% of *Cryptosporidium parvum* at concentrations of less than 10 $\mu$ g/ml. The

determination of the concentration of an agent and the amount of inhibition produced at said concentration is also routine and, thus, within the level of skill of the ordinary artisan in the art. Therefore, the skilled artisan in the art based on the teaching by the cited reference would be able to determine the amount of doxycycline needed to inhibit more than 70% of *Cryptosporidium parvum*.

In summary, the claimed method of use is *prima facie* obvious because of the teachings of the anticryptosporidial activity of doxycycline and the level of skill of the ordinary artisan in the art at the time of the present invention.

For these reasons and those given in Paper No. 8, the rejection of claims 38, 42-51, 54 and 59-70 under 35 USC 103(a) over Armson et al. is maintained and claims 1-5, 9, 12-14, 19, 33-37 and 39-41 are rejected under 35 USC 103(a) over Armson et al.

**10. The rejection of claims 38, 44-51, 54 and 59-70 under 35 USC 103(a) over Armson et al. is made moot by the cancellation of the instant claims.**

***Allowable Subject Matter***

11. Claims 20, 21, 28, 55 and 58 are objected to as being dependent upon a rejected base claim.

Note: the claims are allowable to extent they read on the elected species.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

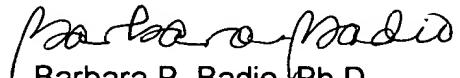
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone Inquiry***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
May 21, 2003